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To: Scott **Date: 3/7/00**
c/o MQSA Hotline
fax 410-290-6351

Re: Comment on Guidance Document 3

Under 21 CFR 900.12 (e)(2) – weekly phantom test (page 20)

In answer to the question regarding the use of AEC or "full automatic" mode, you have required facilities to use "full auto" if that is what is used for patients. The problem is that the ACR phantom is not a patient and is not really even a very good representation of a patient.

I believe that requiring the use of full auto mode with this phantom is ill advised and urge you to reconsider you advice. At least allow AEC as an option. I have been advising facilities to use AEC for the phantom test and would like to continue with this.

You state that "slight variations" of kVp may occur. A change of only ½ kVp results in significantly different mAs which also will cause the unit to fail the test by ACR criteria. In my experience phantom position is not the variable that effects the kVp that is chosen. I am also attaching correspondence between myself and Tom Garvin on this matter.

Thank you for your consideration.

Don Jacobson

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99D-4910

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MEDICAL COLLEGE OF WISCONSIN

Department of Radiology
Medical Physics and Imaging
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April 20, 1999

Thomas W. Garvin
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Food and Drug Administration
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Dear Mr. Garvin:

Thank you for your response to my letter of February 17. You are indeed correct about my error regarding the MQSA requirements for patient notification. I apologize to both you and Ms. North for the accusation of error on her part. I based my opinion on a statement which I heard John McCrohan make in response to a question directed at this very issue. My error was considering that his response was authoritative. I will amend the advice that I give to my clients and in my teaching regarding this MQSA requirement.

On the second issue, with regard to clinical technique, we agree that +/- 1 kVp deviation from the technique chart is not a concern. However, there were four level 3 noncompliance citations given because, "the phantom was not taken at clinical setting." According to a written memo which I received from the site in question, they were advised that "all technologists should be using the same mode, such as AEC or AOP." And further, "if we were using AOP clinically, then the phantom should be taken on AOP." Some technologists will choose the auto mode and some are more comfortable choosing the technique themselves. This should be allowed. I still believe that the fully automatic mode, although effective for patient imaging, is not appropriate for phantom imaging. Putting this question into a guidance document is the way to go and if it comes out for comment, I will submit my reasons for holding the opinion that I do. I have attached a copy of this rationale.

I regret that this exchange has the feeling of being adversarial. I do not intend it to be so. It is my desire that we can support one another in improving the effectiveness of mammography to detect breast cancer as early and accurately as possible.

Sincerely,

Donald R. Jacobson, Ph.D.
Assistant Professor of Radiology

DRJ:mb
Encl.
cc: Ms. Susan North

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APPROPRIATE MODE FOR PHANTOM IMAGING

The standard AEC imaging mode is most appropriate for phantom imaging and accomplishes the goals of the test, namely: to assure consistency of x-ray output, image receptor sensitivity, processing and viewing conditions. A physical (nonpatient equivalent) test object is commonly used which approximates clinical imaging conditions and produces an image which can be quantitatively assessed for image performance parameters such as optical density, contrast, image quality and artifact. The full AEC mode, in which the machine chooses some combination of kVp/anode/filter, depending on the machine, is not appropriate for phantom imaging for the following reasons:

1. The phantom is 4.5 cm thick but presumably represents 4.2 cm of average breast tissue.

2. For one commercial version of the phantom, because of screws used to hold the cover, the compression paddle is positioned at a height of approximately 5 cm above the breast support. Since some manufacturers take the compressed thickness, as indicated by the position of the compression paddle, into account when choosing the kVp, the kVp chosen by the machine with the compression paddle at 5 cm, cannot be correct for 4.2 cm of breast tissue.

3. Some manufacturers choose the kVp such that the exposure time will be within boundaries that are set at installation. In at least one known case, one of those boundaries was very close to the exposure time produced with the phantom at a particular kVp. Therefore, the machine was switching between kVps randomly in order to keep the exposure time within the desire limits. This mode, though appropriate for patient imaging, gave an erroneous impression for the phantom imaging. The MQSA inspector was about to pronounce the machine unfit for imaging. This would have been a terrible mistake since the machine was operating exactly as intended.

The purpose of phantom imaging is to assess the consistency of imaging performance, including image quality, optical density, contrast, artifacts, etc. for a physical test object which approximates, but does not accurately represent clinical imaging conditions. The automatic modes are designed for and are appropriate for patient imaging, but when used with phantom imaging, can cause erratic operation and erroneous conclusions can be drawn.